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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,519	03/16/2004	Donald J. Pinto	PH7513 NP	3202

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EXAMINER

FREISTEIN, ANDREW B

ART UNIT PAPER NUMBER

1626

DATE MAILED: 01/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/801,519

Applicant(s)

PINTO, DONALD J.

Examiner

Andrew B. Freistein

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 16-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-15 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/14/04 & 9/20/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-19 are currently pending in the instant application.

Priority

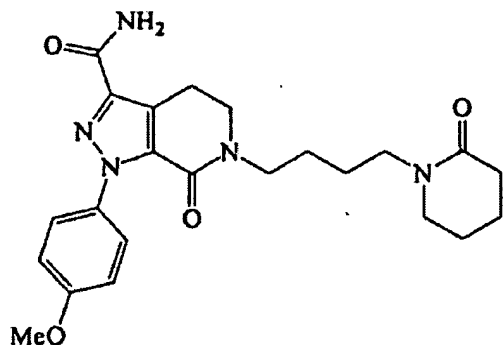
This application is claims benefit of US Provisional Application No. 60/455,708, filed 03/18/2003.

Information Disclosure Statement

Applicant's information disclosure statements (IDSs), filed on June 14, 2004 and September 20, 2004, have been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

Response to Restriction Requirement

Applicant's election of Group I, and the species of Example 60,



, in the reply filed on 11/23/2005 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

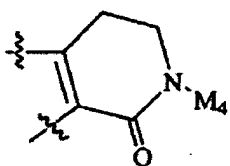
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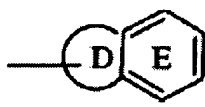
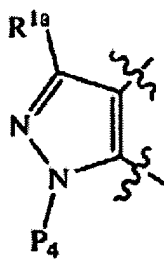
A person shall be entitled to a patent unless –

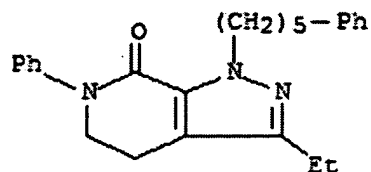
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 9 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Duplantier, WO 95/01980.

The instant invention is drawn to a linear chain substituted monocyclic and bicyclic derivative as a factor Xa inhibitor. Claims 1-3 and 9 claim a compound of

Formula (I), P_4 -P-M- M_4 , wherein M is  ; M_4 is G_1G ; G_1 is absent; G is

Formula IIb,  ; D is absent; E is phenyl; P is  ; P_4 is A-B; A is 2-8 membered linear chain; B is Y; Y is a 3-10 membered carbocycle; R^{1a} is $C(R^3R^{3a})_rR^{1b}$; R^3 , R^{3a} and R^{1b} are H; and r is 2.



Duplantier discloses the compound:

and a

pharmaceutical composition comprising the compound (see Duplantier, STN

International (2006) HCAPLUS Database, Columbus, OH, Accession No. 1995:480325,

Reg. No. 162141-68-6 and WO 95/01980, p. 3, lines 24-28).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

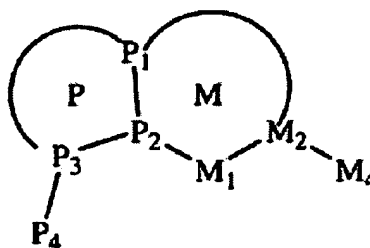
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(1) Claims 1-7 and 9-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to a compound of the formula (I), $P_4-P-M-M_4$, wherein M is a 3-10-membered carbocycle or a 4-10-membered heterocycle consisting of: carbon atoms and 1-3 heteroatoms selected from O, $S(O)_p$, N, and NZ^2 .

The definitions of P_4 , P, M and M_4 , are so broad that they are indefinite, unsearchable, and unclassifiable. There is no clear unambiguous claim to indicate how the variables are bonded to each other and what rings are in each compound. According to the STN search report, there are over 750,000 projected answers for this core structure and no proper search can be performed (see STN International, Columbus, OH, search performed 01/10/2006).

Similarly, claim 2-7 and 9-15 are indefinite for the same reasons as claim 1. For



example, claim 2 is drawn to a formula , wherein ring M, including P_1 , P_2 , M_1 and M_2 is a 5, 6, or 7 membered carbocycle or a 5, 6, or 7 membered heterocycle. Claim 3 is drawn to 105 different structures for variable M and

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44 different structures for variable P. Thus all of claims 1-7 and 9-15 contain widely divergent variables, which creates unsearchable claims.

The claims are unclassifiable, because the variables P_4 , P, M and M_4 , do not indicate a specific ring. For example, compounds containing six-membered hetero rings having two or more heteroatoms of which at least one is N is classified in class 544; compounds containing six-membered hetero rings consisting of one N and five carbon atoms is classified in class 544; and five-membered hetero rings having at least one N atom are classified in class 548. Since the definitions of the variables P_4 , P, M and M_4 define rings of 3-10 members with 0-3 heteroatoms, no proper classification of the compounds of the instant application can be made.

Further, since no proper classification can be made, no prior art search of the class and subclass of claims 1-7 and 9-15 can be made. Therefore, the claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. See MPEP 903.07 and 904 (classification and search).

(2) Claims 1-5 and 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 defines the variable "A" to be a "2-8 membered linear chain consisting of: carbon atoms, 0-2 carbonyl groups, and 0-3 heteroatoms selected from O, N, and $S(O)_p$, and A is substituted with 0-3 R^{1a} and 0-2 R^2 , and there are 0-2 double bonds and 0-1 triple bonds; provided that other than an S-S, S-O, or O-O bond is present in A."

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Claims 2-5 and 9-11 contain similar language in the definition wherein A is a linear chain of Carbon atoms, carbonyl groups, and heteroatoms.

Examiner presumes this "linear chain" is predominantly a carbon-chain, optionally substituted with carbonyl groups and heteroatoms. Under the broadest reasonable interpretation, the chain can consist of Carbon atoms, Nitrogen atoms, Sulfur atoms, and carbonyl groups so long as there are no S-S, S-O, or O-O bonds. However, claims 6, 7 and 11-13 show A to be carbon-only chains. Thus, it is unclear whether claims 2-5 and 9-11 claim variable A to be chain or carbon atoms and heteroatoms, or carbon atoms, optionally substituted with heteroatoms and carbonyl groups.

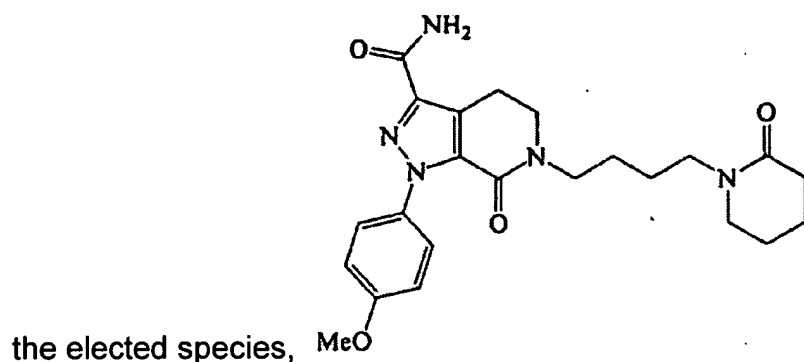
In order to overcome this rejection, Examiner suggests Applicant to define variable A to be:

A 2-8 membered linear chain consisting of carbon atoms wherein there are 0-2 double bonds and 0-1 triple bonds between the carbon atoms, and the chain is optionally substituted with 0-2 carbonyl groups, 0-3 heteroatoms consisting of N, O, and S(O)_p, 0-3 R^{1a} and 0-2 R².

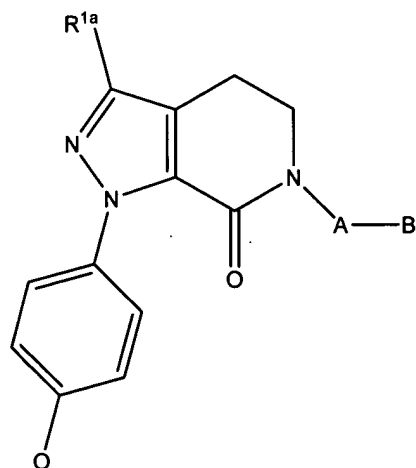
On the other hand, if the linear chain is 2-8 members consisting of carbon atoms, carbonyl groups, and heteroatoms as chain-link members, an clear claim should be written to convey what applicant regards as his invention.

Scope of Prior Art Search

Although claims 1-3, 9 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite, the examiner attempted to search the claims based on



The Examiner searched the elected species and expanded the search to include all of the example compounds in the specification and the compounds of the formula



, wherein A—B and R^{1a} are as defined in claim 1 of the instant application. The Examiner did not find any prior art with respect to compounds of this formula.

Double Patenting

A search of pending applications and issued patents to inventor Donald Pinto was performed. Although the claims are similar in nearly all of the applications and

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patents, the definition of variable "A" in the instant application distinguishes the compounds of the instant application from the other pending applications and issued patents. In the instant application, "A" must be a linear chain and in the other application and patents A is a carbocycle or heterocycle.

Claim Objections

Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form.

Telephone Inquiry

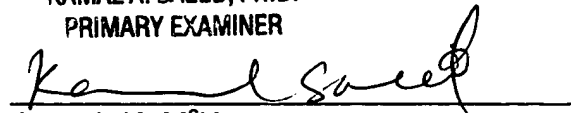
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew B. Freistein whose telephone number is (571) 272-8515. The examiner can normally be reached Monday-Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M^cKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

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Patent Examiner, AU 1626

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER


Joseph K. M^cKane
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Date: January 17, 2006